IsoRay MEDICAL

K092136

AUG 07 2009

3.0 **Section C:** 510(k) Summary Required by 21 CFR § 807.92

3.1 **Submitter**: IsoRay Medical, Inc.

3.2 **Address**: 350 Hills Street, Suite 106
Richland, WA 99354-5411

3.3 **Telephone and Fax Numbers**: 509-375-1202
(Fax) 509-375-3473

3.4 **Contact Person**: Fredric Swindler
fswindler@isoray.com

3.5 **Date of preparation of this Summary**: 07/10/09

3.6 **Device Name, Regulatory and Classification Information**:

3.6.1 **Trade Name**: Proxcelan™ (Cesium-131) Implant Devices, Model PL-5 – Cs-131 Preloaded Braided Strands

3.6.2 **Common Name**: Preloaded Brachytherapy Seeds

3.7 **Classification Name**: Radionuclide Brachytherapy Source (Per 21CFR §892.5730)

3.8 **Marketed device to which equivalence is claimed**: The Proxcelan (Cesium-131) Implant Devices, Model PL-5 – Cs-131 Preloaded Braided Strands that are the subject of this submission are substantially equivalent to the IsoRay Proxcelan™ (Cesium-131) Implant Devices as described in 510(k) No. K062384 (SE 11/09/2006).

3.9 **Product Description**: The Proxcelan (Cesium-131) Implant Devices, Model PL-5 – Cs-131 Preloaded Braided Strands are single use, prescription devices consisting of IsoRay Model CS-1 Brachytherapy Seeds that are preloaded into bioabsorbable braided strands. The Implant Devices are designed to be placed into a body cavity or tissue as a source of nuclear radiation for the treatment of malignant disease. The PL-5 – Cs-131 Preloaded Braided Strands consist of a series of Proxcelan (Cesium-131) Brachytherapy Seeds held in place within a bioabsorbable braided sleeve (or strand). The seeds are arranged in a precise pattern in order to maintain the exact locations and separation distances between the seeds as indicated on a treatment plan prepared by the physician or medical physicist for an individual patient. If required by the treatment plan, the braided strands containing the brachytherapy seeds may be woven into a bioabsorbable mesh supplied as a kit component for implant. A (non-patient contact) needle may also be provided either attached or unattached to the braided strand to attach it to the mesh.

3.10 **Statement of intended use compared to the currently marketed predicate device**: Proxcelan (Cesium-131) Implant Devices, Model PL-5 – Cs-131 Preloaded Braided Strands are single use prescription devices that are intended for medical purposes to be placed onto a body surface or into a body cavity or tissue as a source of nuclear radiation for therapy. This is identical to the legally marketed predicate devices, the IsoRay Proxcelan (Cesium-131) Implant Devices as described in 510(k) No. K062384 (SE 11/09/2006).

3.11 **Statement of Technological Characteristics**: The technical characteristics consist of cesium-131 brachytherapy seeds that are preloaded into braided bioabsorbable sleeves (strands). All materials used in the construction of the Proxcelan (Cesium-131) Implant Devices are biocompatible and currently used in similar marketed devices that are in wide clinical application. The difference between the currently marketed Proxcelan (Cesium-131) Implant Devices and the proposed modification is the addition of a preloaded flexible braided stand instead of the current rigid hollow tubular strand.

3.12 **Safety and Effectiveness**: To ensure that the devices are safe and effective, all finished products are tested and must meet all required release specifications before distribution. The testing required for release includes, but is not limited to leak testing, testing for external contamination, apparent activity, sterility, and labeling. The required testing is defined by written and approved procedures that conform to the product design specifications. The testing for Proxcelan (Cesium-131) Implant Devices, Model PL-5 – Cs-131 Preloaded Braided Strands is detailed in the Device Master Record.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Fredric G. Swindler
Vice President
Regulatory Affairs and Quality Assurance
IsoRay Medical, Inc.
350 Hills St., Suite 106
RICHLAND WA 99354-5411

AUG 0 7 2009

Re: K092136
Trade/Device Name: Proxcelan™ (Cesium-131) Implant Devices,
Model PL-5 – Cs-131 Preloaded Braided Strands
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: July 10, 2009
Received: July 15, 2009

Dear Mr. Swindler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2.0 Section B

Indications for Use

510(k) Number: K092136

Device Name: Proxcelan™ (Cesium-131) Implant Devices, Model PL-5 – Cs-131 Preloaded Braided Strands

Indications for Use:

Proxcelan™ (Cesium-131) Implant Devices, Model PL-5 – Cs-131 Preloaded Braided Strands, containing cesium-131 brachytherapy seeds are indicated for the treatment of malignant disease (e.g. head and neck, brain, breast, lung, prostate, eye, etc.) and may be used in surface, interstitial, and intracavity applications for tumors with known radiosensitivity. These devices may be used as a primary treatment or in conjunction with other treatment modalities, such as external beam radiation therapy, chemotherapy or as a treatment for residual disease after excision of primary tumors.

Prescription Use ___X___ (Per 21 CFR § 801.109) OR Over-The-Counter Use _____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092136